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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/657,404

09/08/2003

Gavin William Halbert

031749/268956

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02/11/2005

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EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

-1653

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/657,404	HALBERT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Hope A. Robinson	1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 16-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/269,533.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |



## **DETAILED ACTION**

### ***Application Status***

1. Applicant's election without traverse of Group I (claims 1-15) on November 19, 2004 is acknowledged. Claims 16-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

### ***Information Disclosure Statement***

2. The Information Disclosure Statements filed on July 19, 2004 and September 8, 2003 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

### ***Drawing***

3. The drawings filed on September 8, 2003 have been accepted by the examiner.

### ***Specification***

4. The specification is objected to because of the following informalities:

(a) The specification is objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic



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terminology. The use of the trademarks such as TRIS®, ZETASIZER®, TRIS®-HCL, for example, have been noted in this application (see pages 21-22 and 36). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

(b) The specification is objected to because on page 25 the following appears "10minutes" which is improperly spaced (see line 25).

(c) The specification is objected to because the priority information that appears on page 1 needs to be updated. For example, Application No. 09/269,533 is now U.S.

Patent No. 6,670,452.

Correction of the above is required.

#### ***Oath/Declaration***

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration, for inventor Moira Doreen Owens. See 37 CFR 1.52(c).

Correction is required.



***Claim Objection***

6. Claims 1, 5, 8 and 10 are objected to because of the following informalities:

(a) For clarity it is suggested that claim 1 is amended to recite "wherein said peptide" in lieu of "wherein the said peptide".

(b) Claim 5 should be amended to recite, "A particle according to claim 1" instead of "A particle according claim 1"

(c) Claim 8 has the following typographical error, "methotrxate" which should be "methotrexate".

(d) Claim 10 is objected to for the recitation of "an hydrophilic substituent", instead of "a hydrophilic substituent".

Correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 9, 11-13 and 15 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.



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(a) Claims 9 and 15 are indefinite for the recitation of "selected from the group" rather than "selected from the group consisting of", which is the proper Markush claim language (i.e. A, B, C or D). Note that the Markush listing is not in the alternative.

(b) Claims 11-13 are indefinite because the claims are incomplete, for the recitation of "amino acid identity". It is suggested that the claim is amended to recite "amino acid sequence identity".

(c) Claim 15 is confusing because it is unclear what are peptides A-F as said peptides are not defined in the claim and the limitations of the specification cannot be read into the claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lundberg et al. (Biochim. Biophys. Acta, vol. 1149, pages 305-312, 1993).

Lundberg teach a non-naturally occurring receptor competent LDL particle comprising a peptide component (apolipoprotein B) wherein the peptide component has a binding site for an Apo B protein receptor and a lipophilic substituent (claim 1, see abstract) . The lipophilic substituent contains cholesterol (claims 7-9 see abstract). The



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presence of hydroxyl, carboxyl, and amino groups is inherent in the amino acids which make up peptides, thus the limitations of claim 10 is met. Since the peptide component of the particle is apolipoprotein B, it is inherent that the peptide has 100% amino acid identity to an Apo B protein binding sequence (claims 11-13). Thus, the reference anticipates the claimed invention.

### ***Basis For NonStatutory Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).



10. Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 11-12 of U.S. Patent No. 6,670,452. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant application claims 1-15 are directed to a non-naturally occurring receptor competent low density lipoprotein particle (LDL) which is bonded to a peptide component having at least one lipophilic substituent and possessing a binding site for Apo B protein receptor (see for example claim 1). The patented claim 1 is directed to the same particle except the scope of the claims differs because the patented claims indicate that the peptide component is covalently bonded and that the lipophilic substituent consist of fatty acids, which reads on claim 9 of the instant application. Furthermore, both the patented claims and the instant application claims are directed to a particle comprising lysine, alanine etc. and analogues thereof (claim 2 of the application). The present application and the patent have claims, which are directed to the size of the peptide component and the percent identity (see claims 3-6 of the instant



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application and claims 3-9 of the patent). Although the instant application recites for example peptide A and the patented claims recite peptide A (SEQ ID NO:3), the two sets of claims are obvious variations of each other as the patented claims recites the name and structure of the peptide, whereas the instant application only recites the name of the peptide.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the same material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, "covalently bonded" in claim 1 because it clarifies the claim by providing the type of bond that is present. Thus, the patented claims are an obvious variation of the instant application claim, therefore prima facie obvious.

### ***Conclusion***

11. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 9:00 a.m. to 6:30 p.m.



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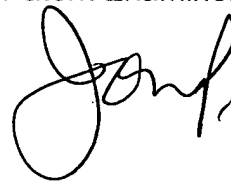
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Patent Examiner



JON WEBER

SUPERVISORY PATENT EXAMINER